

# MENINGOCOCCAL GROUPS A, B, C, W, AND Y VACCINE

## Meningococcal Groups A, B, C, W, and Y Vaccine

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### Alert:

On January 5, 2026, the US Department of Health and Human Services (HHS) announced the approval of a revised US childhood and adolescent immunization schedule ([\(Web\)](#)). Under the revised recommendations, CDC continues to organize the childhood immunization schedule in three distinct categories (Immunizations Recommended for All Children, Immunizations Recommended for Certain High-Risk Groups or Populations, and Immunizations Based on Shared Clinical Decision-Making) but changes individual vaccine placement within those categories. For additional information, see [\(Web\)](#).

## Introduction

Meningococcal groups A, B, C, W, and Y (MenABCWY) vaccine is a pentavalent meningococcal vaccine consisting of a quadrivalent meningococcal serogroup A, C, W, and Y (MenACWY) saccharide-protein conjugate component and a separate serogroup B (MenB) component; both vaccine components are inactivated vaccines containing recombinant antigens from *Neisseria meningitidis*.<sup>1,2</sup>

## Uses

### ■ Prevention of Meningococcal Infection

MenABCWY vaccines are used to stimulate active immunity to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y in individuals 10-25 years of age.<sup>1,2</sup>

There are currently 2 preparations of the pentavalent meningococcal vaccine in the US (Penbraya<sup>®</sup> and Penmenv<sup>®</sup>); each preparation contains a conjugated quadrivalent meningococcal ACWY vaccine component and a serogroup B meningococcal vaccine component.<sup>1,2,3,4</sup> The two US licensed currently available pentavalent meningococcal vaccines, MenACWY-TT/MenB-FHbp (Penbraya<sup>®</sup>) and MenACWY-CRM/MenB-4C (Penmenv<sup>®</sup>), use different carrier proteins for the MenACWY conjugate component and different MenB antigen components.<sup>1,2,3,4</sup> MenACWY-TT/MenB-FHbp (Penbraya<sup>®</sup>) contains MenACWY polysaccharides conjugated to tetanus toxoid (TT) and a meningococcal serogroup B-factor H binding protein vaccine (MenB-FHbp), while MenACWY-CRM/MenB-4C (Penmenv<sup>®</sup>) contains MenACWY oligosaccharides conjugated to CRM197 and a MenB component with 4 antigen components (4C).<sup>1,2,3,4</sup>

### Clinical Experience with MenACWY-TT/MenB-FHbp (Penbraya<sup>®</sup>)

The effectiveness of Penbraya<sup>®</sup> (MenACWY-TT/MenB-FHbp) was assessed in a phase 3, randomized, active-controlled, observer-blinded, multicenter study in participants 10–25 years of age who received either 1) MenACWY-TT/MenB-FHbp at 0 and 6 months or 2) MenB-FHbp (Trumenba<sup>®</sup>) at 0 and 6 months with MenACWY-CRM at 0 months; both MenACWY-naïve and MenACWY-experienced participants were included, but all patients were MenB-naïve.<sup>1,5</sup> The primary immunogenicity endpoint was assessed by measuring the antibody response using the human serum bactericidal activity (hSBA) assay to serogroups A, C, W, and Y, and selected serogroup B strains, assessed 1 month after dose 2; noninferiority of the pentavalent vaccine to MenACWY-CRM plus MenB-FHbp was determined using a prespecified 10% noninferiority margin.<sup>1,5</sup> Seroreponse was defined as a ≥4-fold rise in hSBA titer using baseline values (e.g., baseline hSBA <1:4 required a post-vaccination titer ≥1:16).<sup>1,5</sup> A composite response was defined as an hSBA ≥lower limit of quantitation (LLOQ) for all 4 primary meningococcal B strains.<sup>1</sup>

Seroresponse rates to serogroups A, C, W, and Y following 2 doses of menACWY-TT/MenB-FHbp were noninferior to seroresponse rates following a single dose of MenACWY-CRM, and seroresponse rates and composite response rates to serogroup B following 2 doses of menACWY-TT/MenB-FHbp were noninferior to seroresponse and composite response rates following two doses of MenB-FHbp.<sup>1,5</sup> For serogroups A, C, W, and Y, seroresponse rates after 2 doses of MenACWY-TT/MenB-FHbp were 97.8%, 93.3%, 97.3%, and 94.4%, respectively, in MenACWY-naïve participants and 93.8%, 93.8%, 97.1%, and 93.0%, respectively, in MenACWY-exposed participants.<sup>1</sup> For serogroup B, seroresponse rates after 2 doses of MenACWY-TT/MenB-FHbp were 83.0% (A22 variant), 95.9% (A56 variant), 68.1% (B24 variant), and 86.5% (B44 variant), with a composite post-dose 2 response of 78.3% versus 68.7% with 2 doses of MenB-FHbp.<sup>1</sup>

## Clinical Experience with MenACWY-CRM/MenB-4C (Penmenveny®)

The effectiveness of Penmenveny® (MenACWY-CRM/MenB-4C) was assessed in two phase 3, randomized, active-controlled studies in which participants 10–25 years of age were randomized to receive either 1) MenACWY-CRM/MenB-4C at 0 and 6 months, 2) MenB-4C (Bexsero®) at 0- and 6-months, 3) MenB-4C (Bexsero®) at 0-, 2-, and 6-months or MenACWY-CRM (Menveo®) at 0 months.<sup>2,6</sup> For serogroups A, C, W, and Y, the primary immunogenicity endpoint was assessed by the proportion of individuals achieving an hSBA seroresponse (≥4-fold rise) 1 month after dose 2, and evaluated for noninferiority versus MenACWY-CRM using a prespecified 10% margin in MenACWY-naïve and MenACWY-experienced participants.<sup>2,6,7</sup> Seroresponse rates to serogroups A, C, W, and Y following 2 doses of MenACWY-CRM/MenB-4C were noninferior to seroresponse rates following a single dose of MenACWY-CRM; seroresponse rates after MenACWY-CRM/MenB-4C were 96.7%–97.2% in MenACWY-naïve participants and 94.5%–95.8% MenACWY-experienced patients.<sup>2,6,7</sup> For serogroup B, breadth of immune response was evaluated using the endogenous-complement hSBA (enc-hSBA) assay to evaluate serum bactericidal antibody response against a diverse panel of US MenB strains.<sup>2</sup> MenACWY-CRM/MenB-4C met noninferiority versus MenB-4C for the percentage of tests with bactericidal activity based on the enc-hSBA assay using a prespecified –5% margin (82.5% versus 85.6%).<sup>2</sup> Immune response to MenACWY-CRM/MenB-4C against serogroup B was evaluated with the hSBA assay using indicator strains representative of the 4 antigenic components of MenB-4C.<sup>6</sup> Seroresponse was defined as a ≥4-fold rise in hSBA titer using baseline-dependent criteria (e.g., post-vaccination hSBA ≥4-fold the limit of detection [LOD] or ≥4-fold the lower limit of quantitation [LLOQ], whichever was greater, when pre-vaccination titers were below the LOD).<sup>2,7</sup> In hSBA assays against serogroup B strains, noninferiority (10% margin) was demonstrated for meningococcal serogroup B indicator strains for FHbp (73.2%) and *Neisseria* adhesin A (NadA; 92.7%), but not for *Neisseria* heparin binding antigen (NHBA; 61.8%) or outer membrane vesicles (OMV; 42.2%) strains.<sup>2</sup>

## Clinical Perspective

Pentavalent meningococcal vaccines (Penbraya® and Penmenveny®) provide a single-visit option when both a quadrivalent meningococcal vaccine (MenACWY) and a meningococcal group B vaccine (MenB) are indicated at the same encounter in individuals 10–25 years of age.<sup>3,4</sup> The American Academy of Pediatrics (AAP) and Centers for Disease Control and Prevention (CDC) provide recommendations for the prevention of meningococcal disease caused by *N. meningitidis* serogroups A, B, C, W, and Y.<sup>3,4,199,200,310</sup> AAP and CDC state that adolescents 16–23 years of age not at increased risk may receive a single dose of Penbraya or Penmenveny as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day.<sup>3,4,310</sup> Children 10 years of age and older at increased risk may receive either pentavalent meningococcal vaccine (Penbraya® or Penmenveny®) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day.<sup>3,4,310</sup> Penbraya® or Penmenveny® can be used for booster doses if separated by at least 6 months from the previous dose.<sup>310</sup> Penbraya® and Penmenveny® are not interchangeable.<sup>310</sup> The same type of MenB-containing vaccine for all doses including booster doses should be used.<sup>3,4,310</sup>

## Dosage and Administration

### ■ General

#### Dispensing and Administration Precautions

- Appropriate medical treatment used to manage immediate allergic reactions must be available in the event of an acute anaphylactic reaction following vaccination.<sup>1,2</sup>
- Ensure procedures are in place to avoid a falling injury from syncope after vaccination.<sup>1,2</sup>

#### Other General Considerations

- Syncope (fainting) may occur following vaccination.<sup>1,2,12</sup> Syncope and secondary injuries may be averted if vaccinees sit or lie down during and for 15 minutes after vaccination.<sup>12</sup> If syncope occurs, observe patient until symptoms resolve.<sup>12</sup>

### ■ Administration

There are 2 different pentavalent (MenABCWY) meningococcal vaccines commercially available in the US: MenACWY-TT/MenB-FHbp (Penbraya®) and MenACWY-CRM/MenB-4C (Penmenveny®).<sup>1,2</sup> These vaccines are administered by IM injection only.<sup>1,2</sup>

MenABCWY vaccines may be given concurrently with other age-appropriate vaccines.<sup>9,11</sup> When multiple vaccines are administered during a single health-care visit, give each parenteral vaccine using separate syringes and different injection sites and separate injection sites by >1 inch.<sup>9,11</sup>

In adults and adolescents, IM injections should preferably be made into the deltoid muscle; alternatively, IM injections can be made into the anterolateral thigh.<sup>9</sup>

To ensure delivery into muscle, IM injections should be made at a 90° angle to the skin using a needle length appropriate for the individual's age and body mass, thickness of adipose tissue and muscle at the injection site, and injection technique.<sup>9</sup>

Improper storage or handling of vaccines may reduce vaccine potency resulting in reduced or inadequate immune response in vaccinees.<sup>10</sup> Inspect all vaccines upon delivery and monitor and maintain the appropriate storage temperature.<sup>9</sup>

Do not administer vaccine that has been mishandled or has not been stored at the recommended temperature.<sup>1,1</sup> If there are concerns about mishandling, contact the manufacturer or state or local immunization or health departments for guidance on whether the vaccine is usable.<sup>1,1</sup>

## MenACWY-TT/MenB-FHbp (Penbraya®)

MenACWY-TT/MenB-FHbp is supplied as kit containing a lyophilized MenACWY-TT vial, a prefilled MenB-FHbp syringe, and a vial adapter.<sup>1</sup>

To prepare a dose, remove the vial cap and attach the supplied vial adapter.<sup>1</sup> Shake the prefilled MenB-FHbp syringe vigorously to a white, homogeneous suspension (do not use if it cannot be resuspended).<sup>1</sup> Remove the syringe cap, connect the syringe to the vial adapter, and inject the entire syringe contents into the lyophilized MenACWY-TT vial; gently swirl until the powder dissolves (<1 minute).<sup>1</sup> Invert vial and slowly withdraw entire contents back into the syringe (approximately 0.5 mL), disconnect syringe, and attach a sterile needle for IM administration.<sup>1</sup> Refer to the full prescribing information for complete reconstitution instructions.<sup>1</sup>

After reconstitution, the solution should appear as a homogeneous white suspension (shake to resuspend if not homogeneous) and should be visually inspected for particulate matter or discoloration; discard if either is present.<sup>1</sup>

Administer immediately after reconstitution or store the reconstituted suspension at 2-30°C for ≤4 hours.<sup>1</sup> The vaccine does not contain preservatives; discard if not used within 4 hours.<sup>1</sup> Do not freeze.<sup>1</sup>

Store unopened vials refrigerated at 2-8°C in the original carton; during storage a white deposit/clear supernatant may be seen in the MenB-FHbp syringe, and the carton should be stored horizontally to minimize time needed to resuspend; do not freeze, discard if frozen.<sup>1</sup>

## MenACWY-CRM/MenB-4C (Penmenvy®)

MenACWY-CRM/MenB-4C is supplied as one vial of lyophilized MenACWY-CRM component (powder) and one prefilled syringe of MenB-4C component (liquid), which are combined before administration.<sup>2</sup>

To prepare a dose, invert the MenB-4C prefilled syringe multiple times to form a homogeneous suspension (do not use if it cannot be resuspended), then remove the syringe cap and attach a sterile needle.<sup>2</sup> Cleanse the vial stopper and slowly transfer the entire syringe contents into the vial; without removing the needle, swirl gently until the powder dissolves (do not invert the vial or shake vigorously).<sup>2</sup> After reconstitution, invert the vial and withdraw the entire contents for a single dose (approximately 0.5 mL).<sup>2</sup>

After reconstitution, the vaccine should appear as a white opalescent suspension.<sup>2</sup> Visually inspect for particulate matter or discoloration before administration; do not use if either is present, and administer immediately after reconstitution.<sup>2</sup>

Administer immediately after reconstitution.<sup>2</sup>

Store unopened vials and syringes refrigerated at 2-8°C, away from the freezer compartment, in the original carton to protect from light; do not freeze, discard if frozen.<sup>2</sup>

## ■ Dosage

When both MenACWY and MenB vaccination are indicated at the same visit, either pentavalent MenABCWY vaccine (Penbraya® or Penmenvy®) may be used instead of separate MenACWY and MenB injections.<sup>1,2</sup>

The CDC and ACIP recommend the MenB vaccine series to be completed with a product from the same manufacturer (i.e., MenB-FHbp [Trumenba®] to follow MenACWY-TT/MenB-FHbp [Penbraya®] and MenB-4C [Bexsero®] to follow MenACWY-CRM/MenB-4C [Penmenvy®]).<sup>3,4</sup>

Both pentavalent meningococcal vaccines are administered in 0.5-mL doses.<sup>1,2</sup>

## Prevention of Meningococcal Infection

Pediatric patients ≥10 years of age and adults ≤25 years of age: Administer 2 doses (0.5 mL each) intramuscularly, 6 months apart.<sup>1,2</sup>

## ■ Special Populations

### Hepatic Impairment

The manufacturers make no specific dosage recommendations for individuals with hepatic impairment.<sup>1,2</sup>

### Renal Impairment

The manufacturers make no specific dosage recommendations for individuals with renal impairment.<sup>1,2</sup>

### Geriatric Patients

The manufacturers make no specific dosage recommendations for geriatric individuals.<sup>1,2</sup>

## Cautions

## ■ Contraindications

- MenACWY-TT/MenB-FHbp (Penbraya<sup>®</sup>): Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.<sup>1</sup>
- MenACWY-CRM/MenB-4C (Penmenvy<sup>®</sup>): Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or to any other diphtheria toxoid-containing vaccine.<sup>2</sup>

## ■ Warnings/Precautions

### Management of Allergic Reactions

Appropriate agents and equipment must be available for immediate treatment if an acute allergic reaction, including anaphylactic reactions, occurs following administration of a MenABCWY vaccine.<sup>1,2</sup>

### Syncope

Syncope (fainting) may occur following vaccination.<sup>1,2</sup> Syncope occurs most frequently in adolescents and young adults.<sup>12</sup>

Procedures should be in place to avoid a falling injury following syncope.<sup>12</sup> Syncope and secondary injuries may be averted if vaccinees sit or lie down during and for 15 minutes after vaccination.<sup>12,14</sup> If syncope occurs, the patient should be observed until symptoms resolve.<sup>12,14</sup>

### Altered Immunocompetence

Immune responses to MenACWY-TT/MenB-FHbp or MenACWY-CRM/MenB-4C may be reduced in some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy.<sup>1,2</sup>

Individuals with certain complement deficiencies and those receiving treatment with a complement inhibitor (e.g., eculizumab) are at increased risk for invasive disease caused by meningococcal serogroups A, B, C, W, and Y, even if they develop antibodies following vaccination.<sup>1,2,13,14</sup>

Consult the US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) for specific information on MenABCWY vaccination in individuals with altered immunocompetence (e.g., individuals with human immunodeficiency virus [HIV], those with functional or anatomic asplenia) or individuals receiving immunosuppressant therapy.<sup>3,4,13,14</sup>

### Limitations of Vaccine Effectiveness

MenABCWY vaccines may not protect all vaccine recipients.<sup>1,2</sup> MenABCWY vaccines will not prevent all meningococcal serogroup B strains.<sup>2</sup>

### Guillain-Barre Syndrome

Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of another US quadrivalent polysaccharide meningococcal conjugate vaccines.<sup>1,2</sup>

The decision to administer a MenABCWY vaccine in an individual with a history of GBS should take into account the potential benefits and risks.<sup>1,2</sup>

### Tetanus Immunization

Although MenACWY-TT/MenB-FHbp (Penbraya<sup>®</sup>) contains meningococcal antigens conjugated to tetanus toxoid, the vaccine is not a substitute for routine tetanus immunization.<sup>1</sup>

## Specific Populations

### Pregnancy

*MenACWY-TT/MenB-FHbp: There are no clinical studies evaluating MenACWY-TT in pregnant women.<sup>1</sup> Clinicians are encouraged to report MenACWY-TT/MenB-FHbp exposure that occurs during pregnancy to the manufacturer's pregnancy registry at 1-877-390-2953.<sup>1</sup>*

*MenACWY-CRM/MenB-4C: There are no adequate and well-controlled studies evaluating MenACWY-CRM in pregnant women.<sup>2</sup>*

*CDC and ACIP recommend MenACWY-TT or MenACWY-CRM if needed during pregnancy and the vaccine cannot be deferred.<sup>3,4</sup>*

### Lactation

*It is not known whether MenACWY-TT/MenB-FHbp or MenACWY-CRM/MenB-4C is distributed into human milk.<sup>1,2</sup> Data are not available to assess the effects of MenACWY-TT/MenB-FHbp or MenACWY-CRM/MenB-4C on the breast-fed infant or on milk production.<sup>1,2</sup>*

*The benefits of breastfeeding and the importance of MenABCWY vaccine to the woman should be considered along with the potential adverse effects on the breast-fed child from the vaccine or from the underlying maternal condition (i.e., susceptibility to meningococcal infection).<sup>1,2</sup>*

## Pediatric Use

*MenACWY-TT/Men-FHbp: Safety and efficacy have not been established in children <10 years of age; in one clinical study of a reduced-dose formulation of meningococcal group B vaccine (Trumenba<sup>®</sup>) in infants <12 months of age, 90% developed fever.<sup>1</sup> MenACWY/Men-FHbp contains the same MenB component at the same quantity as MenB-4C (Trumenba<sup>®</sup>).<sup>1</sup>*

*MenACWY-CRM/Men-4C: Safety and effectiveness have not been established in children <10 years of age.<sup>2</sup>*

## Geriatric Use

*MenACWY-TT/Men-FHbp and MenACWY-CRM/Men-4C: The safety and efficacy have not been established in adults >65 years of age.<sup>1,2</sup>*

## Common Adverse Effects

MenACWY-TT/Men-FHbp: The most commonly reported (≥15%) adverse reactions after dose 1 and dose 2, respectively, were pain at the injection site (89% and 84%), fatigue (52% and 48%), headache (47% and 40%), muscle pain (26% and 23%), injection site redness (26% and 23%), injection site swelling (25% and 24%), joint pain (20% and 18%), and chills (20% and 16%).<sup>1</sup>

MenACWY-CRM/Men-4C: The most commonly reported (≥10%) solicited adverse reactions after dose 1 and dose 2, respectively, in individuals 10-25 years of age were pain at the injection site (92% and 88%), fatigue (51% and 42%), headache (42% and 36%), myalgia (15% and 12%), nausea (15% and 10%), erythema (13% and 12%), and swelling (13% and 12%); and after dose 1 and 2, respectively, in individuals 15-25 years of age were pain at the injection site (80% and 74%), headache (41% and 33%), fatigue (40% and 33%), myalgia (15% and 13%), and nausea (15% and 12%).<sup>2</sup>

## Drug Interactions

### Immune Globulins

The US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) states that inactivated vaccines such as meningococcal groups A, B, C, Y, and W vaccine (MenABCWY vaccine) may be given concurrently using separate syringes and different injection sites or at any interval before or after immune globulin preparations.<sup>9,13,14</sup>

ACIP states that patients with quantitative B-cell deficiencies should not receive inactivated vaccines while receiving immune globulin therapy due to concerns about vaccine effectiveness.<sup>13,14</sup>

### Immunosuppressive Agents

Immune responses to vaccines, including MenABCWY vaccine, may be reduced in individuals receiving immunosuppressive therapy (e.g., alkylating agents, antimetabolites, corticosteroids at greater than physiologic dosages, cytotoxic drugs, radiation).<sup>13,14</sup>

CDC and ACIP guidance states that non-live vaccines generally can be safely administered in persons with altered immunocompetence, but vaccine effectiveness may be suboptimal.<sup>13,14</sup> This includes patients receiving chemotherapy, radiation therapy, anti-B-cell antibodies (e.g., rituximab), immunoglobulin therapy, and other immunosuppressive or immunomodulatory therapies such as interleukins, colony-stimulating factors, and tumor necrosis factor-alpha inhibitors.<sup>13,14</sup>

Persons vaccinated within 14 days before starting immunosuppressive therapy, or while receiving immunosuppressive therapy, should be revaccinated at least 3 months after immunotherapy is discontinued provided immune competence was restored.<sup>13,14</sup>

For patients receiving chemotherapy with anti-B-cell antibodies (e.g., rituximab), non-live vaccines should generally be deferred for at least 6 months after therapy (and some experts recommend longer for certain anti-B-cell agents).<sup>13,14</sup>

### Vaccines

CDC and ACIP guidance states that meningococcal vaccines may be administered during the same visit as other vaccines, provided separate syringes and different injection sites are used.<sup>9,11</sup>

## Description

Meningococcal groups A, B, C, W, and Y (MenABCWY) vaccines are inactivated combination vaccines that stimulate active immunity to invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y.<sup>1,2</sup> Two MenABCWY vaccines are currently available: MenACWY-TT/MenB-FHbp (Penbraya<sup>®</sup>) and MenACWY-CRM/MenB-4C (Penmenvry<sup>®</sup>).<sup>1,2</sup> Both products combine a MenACWY conjugate component with a MenB component and are supplied as a 2-component product (a lyophilized MenACWY component plus a liquid MenB component) that must be combined before administration.<sup>1,2</sup>

Protection against invasive meningococcal disease is conferred mainly by complement-mediated antibody-dependent killing of *N. meningitidis*.<sup>1,2</sup> MenACWY-TT/MenB-FHbp (Penbraya<sup>®</sup>) induces antibodies against meningococcal serogroups A, C, W, and Y capsular polysaccharides and against meningococcal serogroup B factor H binding protein (FHbp) variants from subfamilies A and B.<sup>1</sup> MenACWY-CRM/MenB-4C (Penmenvry<sup>®</sup>) induces antibodies against meningococcal serogroups A, C, W, and Y capsular oligosaccharides and against meningococcal serogroup B antigens *Neisseria* heparin binding antigen (NHBA), *Neisseria* adhesin A (NadA), FHbp, and outer membrane vesicles (OMV).<sup>2</sup> For both vaccines, coverage of meningococcal serogroup B strains depends on antigenic similarity and antigen expression by circulating strains.<sup>1,2</sup>

The products differ in carrier protein and MenB antigen composition.<sup>1,2</sup> MenACWY-TT/MenB-FHbp (Penbraya<sup>®</sup>) uses tetanus toxoid (TT) as the MenACWY carrier protein and contains 2 recombinant lipidated FHbp variants in the MenB component.<sup>1</sup> MenACWY-CRM/MenB-4C (Penmenvy<sup>®</sup>) uses *Corynebacterium diphtheriae* CRM197 as the MenACWY carrier protein and contains recombinant NHBA, NadA, and FHbp proteins plus OMV in the MenB component.<sup>2</sup>

Both vaccines are administered IM as a 2-dose series given 6 months apart.<sup>1,2</sup> Immune responses may be reduced in immunocompromised individuals, and persons with complement deficiencies or those receiving terminal complement inhibitors remain at increased risk for invasive meningococcal disease despite vaccination.<sup>1,2,13,199,200</sup> Vaccine effectiveness may be incomplete, and protection against all serogroup B strains is not assured.<sup>1,2,13</sup>

## Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from [MedlinePlus](#) (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Prior to administration, provide a copy of the appropriate Centers for Disease Control and Prevention (CDC) Vaccine Information Statement (VIS) to the patient or patient's parent or guardian (VISs are available at the CDC website at [\[Web\]](#) ).<sup>1,2</sup>
- Inform vaccine recipient of the potential benefits, importance of completing the immunization series, and risks of vaccination with MenABCWY vaccine.<sup>1,2</sup>
- Advise the patient and/or patient's parent or guardian that routine meningococcal vaccination is recommended in the US for all adolescents at 11-12 years of age, followed by a booster dose at 16 years of age; catch-up vaccination is recommended at 13-18 years of age for those not previously vaccinated.<sup>3,4</sup> Also advise that meningococcal vaccine is recommended for certain individuals at increased risk for exposure to meningococcal disease (e.g., individuals with certain chronic medical conditions, international travelers, health-care or laboratory workers, unvaccinated or under vaccinated first-year college students living in residence halls, military personnel) or during an outbreak.<sup>3,4</sup>
- Advise the patient and/or patient's parent or guardian that revaccination or booster doses of MenABCWY vaccine may be needed in individuals who receive primary immunization and remain at prolonged increased risk for disease caused by meningococcal serogroups A, B, C, Y, and W.<sup>3,4</sup> Pentavalent MenABCWY vaccines (Penbraya<sup>®</sup> and Penmenvy<sup>®</sup>) may be used when both MenACWY and MenB are indicated at the same visit in an eligible patient.<sup>3,4</sup>
- Advise the patient and/or patient's parent or guardian that MenABCWY vaccine may not provide protection in all vaccine recipients.<sup>1,2,3,4</sup>
- Advise the patient and/or the patient's parent or guardian that fainting (sometimes resulting in falling with injury) has been reported following vaccination, and that patients should sit or lie down during and for 15 minutes after vaccine administration.<sup>1,2,12</sup>
- Advise the patient and/or the patient's parent or guardian to inform clinicians of a history of allergic reactions to MenABCWY vaccine or any vaccine component.<sup>1,2,3,4</sup>
- Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and [\[Web\]](#) .<sup>1,2</sup> If administered MenACWY-CRM/MenB-4C (Penmenvy<sup>®</sup>) also report to GlaxoSmithKline at 1-888-825-5249.<sup>2</sup>
- Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary or herbal supplements, as well as any concomitant illnesses.<sup>1,2</sup>
- Advise patients to inform their clinician if they are or plan to become pregnant or plan to breast-feed.<sup>1,2</sup>
- Inform patients of other important precautionary information.<sup>1,2</sup>

## Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

## Preparations

*Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.*

### ***Meningococcal Group A, B, C, W, and Y Vaccine***

<b><i>ROUTES</i></b>	<b><i>FORMS</i></b>	<b><i>STRENGTHS</i></b>	<b><i>BRAND NAMES</i></b>	<b><i>MANUFACTURER</i></b>
<i>Parenteral</i>	<i>Injection, for IM use</i>	<i>5 mcg each of meningococcal A, C, Y, W-135 capsular polysaccharides conjugated to 44 mcg of tetanus toxoid protein carrier per 0.5 mL</i>	<i>Penbraya<sup>®</sup></i>	<i>Pfizer Laboratories</i>









		<i>(MenACWY-TT) and 2 recombinant lipidated factor H binding protein variants from N. meningitidis serogroup B (60 mcg each) per 0.5 mL</i>		
Parenteral	Injection, for IM use	10 mcg of meningococcal A and 5 mcg each of meningococcal C, Y, W-135 capsular oligosaccharides conjugated to diphtheria CRM <sub>197</sub> protein carrier per 0.5 mL (MenACWY-CRM) and 3 recombinant serogroup B proteins (50 mcg each) and outer membrane vesicles (25 mcg) from N. meningitidis serogroup B per 0.5 mL	Penmenvy <sup>®</sup>	GlaxoSmithKline

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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